CHILDRENS MUCINEX CONGESTION AND COUGH- dextromethorphan hydrobromide, guaifenes in, and phenylephrine hydrochloride solution Reckitt Benckis er LLC

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

Children's Mucinex® Congestion & Cough

Drug Facts

Active ingredients (in each 5 mL)	Purposes
Dextromethorphan HBr 5 mg	Cough suppressant
Guaifenesin 100 mg	Expectorant
Phenylephrine HCl 2.5 mg	Nasal decongestant

Uses

- helps loosen phlegm (mucus) and thin bronchial secretions to rid the bronchial passageways of bothersome mucus and make coughs more productive
- temporarily relieves:
 - cough due to minor throat and bronchial irritation as may occur with the common cold or inhaled irritants
 - the intensity of coughing
 - the impulse to cough to help your child get to sleep
 - nasal congestion due to a cold
 - stuffy nose

Warnings

Do not use in a child who is taking a prescription monoamine oxidase inhibitor (MAOI) (certain drugs for depression, psychiatric, or emotional conditions, or Parkinson's disease), or for 2 weeks after stopping the MAOI drug. If you do not know if your child's prescription drug contains an MAOI, ask a doctor or pharmacist before giving this product.

Ask a doctor before use if the child has

- heart disease
- high blood pressure
- thyroid disease
- diabetes
- cough that occurs with too much phlegm (mucus)
- persistent or chronic cough such as occurs with asthma

When using this product do not use more than directed

Stop use and ask a doctor if

- your child gets nervous, dizzy or sleepless
- symptoms do not get better within 7 days or occur with fever
- cough lasts more than 7 days, comes back, or occurs with fever, rash, or persistent headache. These could be signs of a serious illness.

Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control

Center right away.

Directions

- do not take more than 6 doses in any 24-hour period
- measure only with dosing cup provided
- do not use dosing cup with other products
- dose as follows or as directed by a doctor
- mL = milliliter

Age	Dose
children 6 years to under 12 years	10 mL every 4
	hours
children 4 years to under 6 years	5 mL every 4 hours
children under 4 years	do not use

Other information

- each 5 mL contains: sodium 3 mg
- tamper evident: do not use if neckband on bottle cap is broken or missing
- store between 20-25°C (68-77°F)
- do not refrigerate
- dosing cup provided

Inactive ingredients

anhydrous citric acid, edetate disodium, FD&C Red #40, flavors, glycerin, propylene glycol, propyl gallate, purified water, sodium benzoate, sorbitol, sucralose, trisodium citrate dihydrate¹, xanthan gum

Questions?

1-866-MUCINEX (1-866-682-4639)

You may also report side effects to this phone number.

Dist. by: Reckitt Benckiser, Parsippany, NJ 07054-0224

Made in England

PRINCIPAL DISPLAY PANEL - 201 mL Bottle Carton

NDC 63824-283-67

Children's

Mucinex®

Congestion & Cough

Dextromethorphan HBr 5 mg Guaifenes in 100 mg Phenylephrine HCl 2.5 mg Cough Suppressant Expectorant Nasal Decongestant

¹ may contain this ingredient

- Chest Congestion
- **Breaks up Mucus**
- ☐ Stuffy Nose
- Cough

Age 4+

Berrylicious Flavor Liquid

6.8 FL OZ (201 mL) Tamper evident: do not use if neckband on bottle cap is broken or missing,

Children's **Mucin∈**X

Congestion & Cough

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Cough Suppressant Expectorant Nasal Decongestant

NOC 63824-283-67

Children's **Mucin∈**×

Congestion & Cough

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Expectorant Nasal Decongestant

- ✓ Chest Congestion
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Drug Facts (continued)

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Also look for Children's **Mucin∈**X



Great-tasting chest-congestion relief in fun-to-take, convenient granule packets!



Dist. by: Reckitt Benckiser, Parsippany, NJ 07054-0224 ©2013 RB 080113 3000462 LOT CODE: EXP. DATE: 3000462

Children's Mucinex

Congestion & Cough



DOSING CUP INCLUDED

Each dose of berrylicious-flavored Children's Mucinex®

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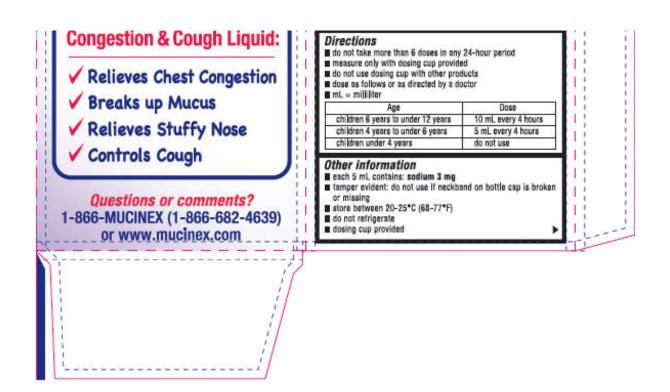
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CHILDRENS MUCINEX CONGESTION AND COUGH

dextromethorphan hydrobromide, guaifenesin, and phenylephrine hydrochloride solution

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:63824-283	
Route of Administration	ORAL			

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
Dextromethorphan Hydrobromide (UNII: 9 D2RTI9KYH) (Dextromethorphan - UNII:7355X3ROTS)	De xtro metho rpha n Hydro bro mide	5 mg in 5 mL	
Guaifenesin (UNII: 495W7451VQ) (Guaifenesin - UNII:495W7451VQ)	Guaifenesin	100 mg in 5 mL	
Phenylephrine Hydrochloride (UNII: 04JA59TNSJ) (Phenylephrine - UNII:1WS297W6MV)	Phenylephrine Hydrochloride	2.5 mg in 5 mL	

Inactive Ingredients			
Ingredient Name	Strength		
anhydrous citric acid (UNII: XF417D3PSL)			
edetate disodium (UNII: 7FLD91C86K)			
FD&C red no. 40 (UNII: WZB9127XOA)			
glycerin (UNII: PDC6A3C0OX)			
propylene glycol (UNII: 6DC9Q167V3)			
propyl gallate (UNII: 8D4SNN7V92)			
water (UNII: 059QF0KO0R)			
sodium benzoate (UNII: OJ245FE5EU)			
sorbitol (UNII: 506T60A25R)			
sucralose (UNII: 96K6UQ3ZD4)			

п		
	trisodium citrate dihydrate (UNII: B22547B95K)	
	xanthan gum (UNII: TTV12P4NEE)	

Product Characteristics			
Color	PINK	Score	
Shape		Size	
Flavor	BERRY	Imprint Code	
Contains			

P	Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:63824-283-67	1 in 1 CARTON			
1		201 mL in 1 BOTTLE			

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part341	07/17/2012	

Labeler - Reckitt Benckiser LLC (094405024)

Revised: 10/2013 Reckitt Benckiser LLC